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#### **REMARKS**

Applicant has reviewed the outstanding Office Action and its contents have been carefully noted. Applicant acknowledges that the Examiner has withdrawn his objections under 35 U.S.C. §112 in view of the previous amendments to the drawings, specification and claims.

#### Rejection under 35 U.S.C. §112

The Examiner rejected claim 168 under §112, second paragraph, as being indefinite. Specifically, the Examiner stated that the phrase "out of the device" is vague because there is no sample outlet in the main independent claim. Applicant has amended claim 168 and deleted this phrase from the claim. The newly amended claim 168 renders the rejection moot, and Applicant requests withdrawal of the rejection.

#### Rejections under 35 U.S.C. §102(e)

The Examiner rejected claims 163-165, 167-169, 171, and 173-178 as being anticipated by Wilding et al. (U.S. 5,726,026). According to the Examiner, Wilding et al. describe a sample device

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having no sample outlet. The Examiner refers to Figure 8A in Wilding et al., and states, *inter alia*, "although the Wilding et al. reference does not explicitly disclose that the device has no sample outlet, Figure 8A discloses a device that comprises several inlet ports, but no outlet ports, thereby teaching a device without a sample outlet." Applicant strongly disagrees with the Examiner's characterization of Figure 8A in Wilding et al. and traverse this rejection.

Figure 8A in Wilding et al. is described in col. 6, lines 32-36, as having "two mesoscale flow systems, each one including inlet ports interconnected by a flow channel to a single chamber for analyte capture and optionally detection." One cannot have liquid flow in a channel without an opening for liquid to enter, and another opening for liquid to exit the channel. Applicant must stress that what Wilding et al. describe as "inlet ports" in Fig. 8A are, in fact, openings into the device for liquid to either enter or exit the device.

It is clear when reading the specification of Wilding et al., that some of the inlet ports marked "133" in fact function as an outlet port. For example, see Wilding et al. at column 13, line 62, to column 14, line 4, in which the immobilized reagent is

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introduced in chamber 135. The specification teaches that the chamber is filled with a second fluid, through one of the two inlet ports 133 with a test sample (expelling the first fluid), followed by a third fluid (antibody enzyme conjugate) and subsequently a fourth fluid (solution of chromogenic substrate) is also added to expel the previous fluid. The only way in which the first and later subsequent fluids can leave the device in Fig. 8A when the next fluid is added, is by being forced out of the device through the second "inlet port" 133 at the bottom (of Fig. 8A) of the channel. The second "inlet port" is actually functioning as an outlet port, regardless of the label given the structure by the inventors or their patent attorney.

Further support for this outlet function is found at column 14, lines 27-39 of the specification, where it states, "...the design is such that fluid can be pumped over and through the immobilized reagent for washing purposes". This embodiment, the pumping of a fluid through the chamber, is only possible if at least one of the inlet ports 133 functions as an outlet port.

Finally, from the description of the device of Figure 8A in Wilding et al., it is clear that liquid must exit the device through a second opening or outlet, because Wilding et al. put

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great emphasis on an particular embodiment where reagents (such as antibody coated beads) can be immobilized in the chamber 135.

Wilding et al. describe that this embodiment can be accomplished using a stationary support, or by using coated particles that are too large to leave through flow channels 132a, 132b (col. 13, lines 46-55). Moreover, there is a third opening shown in Fig. 8A, port 137 that is used to allow larger particles to gain access to the chamber 135 that cannot fit through the flow channels 132a, 132b. This embodiment in Wilding et al. would be completely inoperable if none of the ports 133 of the device of Figure 8A functioned as a fluid outlet, because the reagents could never leave the device, regardless of whether or not attached to any stationary support or large polymer particles.

As can be seen from the foregoing discussion, the device taught in Wilding et al. has not one, but three openings. While all these openings are labelled as "inlets", at least one functions as an "outlet" for liquid to flow through the device in every embodiment.

Therefore, Wilding et al. does not teach or suggest a device without a sample outlet. The present invention, in claim 163, has only one opening for a liquid analyte to enter. There is

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no other opening to allow liquid to leave the device. Therefore, because Wilding et al. does not teach all of the elements of claim 163 it cannot anticipate the claim, and Applicant respectfully requests withdrawal of the rejection. Additionally, since the other rejected claims (164, 165, 167-169, 171, and 173-178) are dependent from claim 163 and also contain the same limitation of having no sample outlet, Wilding et al. cannot anticipate these claims for the reasons stated above.

With regard to claim 169, Applicant further submits that Wilding et al. do not teach a device comprising a means for performing one or more operations on the liquid sample, the operations being selected from the group consisting of filtration, concentration, and magnetic attraction. The Examiner referred to column 9, line 6; column 5, lines 31-32, and column 9, lines 29-33 of Wilding et al. However, these sections all relate to the sample preparation device disclosed in Wilding et al., and not to the assay device therein. Wilding et al. do not disclose an assay device (i.e. a device also having an exposing domain) with these features. Furthermore, column 5, lines 31-32 of Wilding et al. relates to determination of a concentration of an analyte in the sample, not to concentrating the sample. Thus, these elements are

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not taught or suggested by Wilding et al. and therefore cannot be anticipated.

The Examiner further stated that Wilding et al. describe a device as defined in claims 173 and 177. Applicant respectfully disagrees. In addition to the fact that Wilding et al. do not teach a device having no sample outlet, Wilding et al. also do not teach or suggest a device, wherein the volume of the sample compartment from which electromagnetic radiation is exposed, is in the range between 0.01  $\mu$ l and 20  $\mu$ l (claim 173) or between 0.04  $\mu$ l and 4  $\mu$ l (claim 177).

In the rejection, the Examiner points to column 16, lines 56-60 of Wilding et al. for support. However, this section of Wilding et al. refers to the volume of the metering chamber, and not to the volume of the detection chamber 183. It is the volume of the detection chamber that is relevant here, since that is the compartment through which electromagnetic radiation is directed. Wilding et al. do not disclose any specific volume of the detection chamber. Thus, the ranges specified in claim 173 and 177 cannot be anticipated by Wilding et al. In view of the foregoing, Applicant respectfully requests that all of the Examiner's rejections under 35 U.S.C. §102(e) be withdrawn.

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Rejections under 35 U.S.C. §103

The Examiner has maintained his rejection of claim 166 as obvious over Wilding et al. in view of Yager et al. (US 5,716,852). The rejection is respectfully traversed.

As discussed above, Wilding et al. do not teach devices without a sample outlet. In response to the foregoing anticipation rejection, Applicant showed that the sample preparation devices as well as the detection devices and polynucleotide amplification devices associated therewith in Wilding et al., all comprise a plurality of openings, some of which function as an outlet.

The burden is on the Examiner to establish a *prima facie* case of obviousness of the claimed subject matter over prior art references. In re Deuel, 51 F.3d 1552, 1557, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995). Only after that burden is met must Applicant come forward with arguments or evidence in rebuttal. Id. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Applicant respectfully submits that Yager et al. (US 5,716,852) and Kricka et al. (US 5,744,366) do not teach devices

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without a sample outlet. Moreover, Masuda et al. (US 4,472,498), Ozaki et al. (US 5,754,289), Fesik et al. (US 5,804,390) and Allen et al. (US 5,190,857) also do not teach devices without sample outlet.

As such, Applicant believes that the Examiner has failed to establish a *prima facie* case of obviousness with regard to claim 166 because the combination of Wilding et al. in view of Yager et al. does not teach each and every element of the claimed invention. In this case, the combination of references do not teach or suggest analysis of a sample in a device having no sample outlet. The secondary references all teach analysis of a flowing sample stream. Such a device combination as taught or suggested in the cited references would be inoperable, as a flowing sample stream could not exist in a device without a sample outlet.

In the Examiner's remarks in the outstanding Office Action, the Examiner rebutted Applicant's statements regarding non-obviousness of the claimed invention and cited In re Keller, 642 F.2d 413; 208 USPQ 871 (CCPA 1981). The Examiner stated that Applicant did not properly attack the combination of references. Applicant respectfully disagrees.



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In Keller, the applicant argued that the primary reference did not teach or suggest the use of digital timing in a pacemaker. However, in Keller, unlike the present invention, the secondary references taught all of the claimed limitations not present in the primary reference, and the CCPA upheld the rejection. That is not the case here. The deficiencies of Wilding et al. are not cured by the addition of the secondary references. The present situation is more along the lines of Ex parte Futo, 59 USPQ2D 1955 (BPAI 2000) ("For the reasons set forth above, we do not agree with the Examiner that Vollers (the primary reference) discloses all of the subject matter recited in claim 1 except for the engaging surfaces in the wrench body, in that it does not disclose or teach the construction required by the final seven lines of the claim. This deficiency is not cured by further considering Moulin, Goss or Gilbert (the secondary references)").

The Examiner's obviousness rejection appears to be based on the premise that Applicant's understanding of Wilding et al. was mistaken and therefore no sample outlet is disclosed. As discussed above, Wilding et al. does in fact disclose at least one port that functions as an outlet. All of the limitations in claim 166 are not taught or suggested by the combination of Wilding et

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al. in view of Yager. Applicant therefore respectfully requests that this rejection be withdrawn.

The Examiner has maintained his rejection of claim 170 under 35 U.S.C. §103(a) as obvious over Wilding et al., in view of Masuda et al. (US 4,472,498), Ozaki et al. (US 5,754,289), Fesik et al. (US 5,804,390) and Allen et al. (US 5,190,857). Applicant respectfully traverses this rejection.

As stated above in regard to claim 166, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness with regard to claim 170 because the combination of Wilding et al. in view of Masuda et al. Ozaki et al., Fesik et al. and Allen et al. does not teach each and every element of the claimed invention. In this case, the combination of references does not teach or suggest spectrophotometric measurement of a sample in a device having no sample outlet. The secondary references all teach spectrophotometric or similar analyses of a flowing sample stream. All of the limitations in claim 170 are not taught or suggested by the combination of references, and therefore Applicant respectfully requests that this rejection be withdrawn.

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The Examiner has maintained his rejection of claim 172 under 35 U.S.C. §103(a) as obvious over Wilding et al., in view of Kricka et al. (US 5,744,366). The Examiner states that at the time of the invention, it would have been obvious to one of skill in the art to include in the device of Wilding, a device with chambers having widths and lengths on the order of 1 mm or larger, wherein the chamber is fabricated in a substrate and a cover is disposed over the substrate as taught by Kricka, in order to allow adequate cell movement within the chamber. Applicant respectfully traverses this rejection.

As stated above in regard to claim 166 and 170, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness with regard to claim 172 because the combination of Wilding et al. in view of Kricka does not teach each and every element of the claimed invention. In this case, the combination of references do not teach or suggest the limitation of the chamber dimensions in a device having no sample outlet. All of the limitations in claim 172 are not taught or suggested by the combination of references, and therefore Applicant respectfully requests that this rejection be withdrawn.

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All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all currently outstanding rejections, and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

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If the remittance herewith is incorrect in any fashion,  
kindly debit or credit Deposit Account No. 06/1358 appropriately  
and advise the undersigned accordingly.

Respectfully submitted,

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